REMARKS

I. Response to Amendment

In response to Applicants' communication, filed May 24, 2004, the obviousness rejection under 35 U.S.C. §103 based on the combination of US 5,750,996 to Drennen, III et al. ("Drennen"), US 5,748,311 to Hamann et al., US 5,784,160 to Naqui and the publication Link et al., "Fluidized bed spray granulation: Investigation of the coating process on a single sphere", Chemical Engineering and Processing, 36 (1997), pp. 443-457 was withdrawn. (See the Office Action, Paragraph 10 at page 9).

II. Claim Rejection – Double Patenting

Obviousness-type double patenting is the only rejection set forth in the outstanding Office Action. All pending claims are rejected for obviousness-type double patenting in view of a combination of two or more patents. Each double patenting rejection is at least based on the commonly owned US 6,633,792 (the "'792 patent"), issued October 14, 2003, to Folestad et al. ("Folestad") in combination with Drennen. With respect to certain claims, Folestad and Drennen are combined with yet a third and fourth reference to support the rejection. The double patent rejections are summarized in the following table:

CLAIMS	CITED PATENTS	
1, 2, 7-9, 13-18, 20, 22-25, 27, 31, 32, 37-39, 41, 47, 48 and 53	Folestad + Drennen	
4-6, 28-30, 35 and36	Folestad + Drennen	US 4,125,391 to Van Laethem ("Van Laethem")
10, 33, 42-44 and 50	Folestad + Drennen	US 4,993,264 to Cody et al. ("Cody")
11 and 45	Folestad + Drennen	US 6,038,525 to Maguire et al.
12, 34, 46 and 52	Folestad + Drennen	Van Laethem + US 6,248,363 to Patel et al.
19 and 40	Folestad + Drennen	US 5,420,681 to Woodruff
49 and 51	Folestad + Drennen	Van Laethem + Cody

III. Applicable Principle of Law

With respect to obviousness-type double patenting, the inquiry is whether the claimed invention would have been obvious from the claims of Folestad in light of the prior art. Ortho Pharm Corp. v. Smith, 959 F.2d 936 (Fed. Cir. 1992).

IV. The Claimed Invention

As discussed in detail on pages 3-4 of Applicants' communication, filed May 24, 2004, the claimed invention is characterized by the concurrent performance of three process steps:

(a) a particle levitates or floats at a given location;
(b) the ***same*** particle is coated while it levitates or floats at the given location; and
(c) a spectroscopic measurement is performed on the coating while the ***same*** particle levitates or floats at the given location.

V. Folestad

Claim 1 of Folestad defines a method of controlling the process of manufacturing a coating on a pharmaceutical product by monitoring principal parameters relating to properties of the coating, e.g., physical and chemical properties, permeability, stability, etc., by performing a spectrometric measurement on the coating. Claim 9 provides that the measurement can be taken at any stage of the coating process.

As acknowledged by the Examiner, none of the claims of Folestad discloses or suggests the concurrent performance of process steps (a), (b) and (c) of the claimed invention. Specifically, the Examiner stated:

> [Folestad] fails to teach that the coating vessel is a fluidized bed and the sample of the pharmaceutical product is a particle so that the spectromctric measurement is performed on a single pharmaceutical particle while coating within the fluidized bed.

(Office Action, at page 3).

VI. Drennen

The Examiner alleges that Drennen discloses that a spectrometric measurement can be used for monitoring the coating of a single pharmaceutical dosage unit, e.g., a pellet, tablet or capsule, while the dosage unit is being coated within a fluidized bed. (Office Action at page3).

First, Applicant respectfully submits that the Examiner's present interpretation of Drennen is inconsistent with the Examiner's previous interpretation of Drennen. At page 3 of the Office Action, mailed January 23, 2004, the Examiner stated that:

> Drennen, III et al fail to teach that the spectrometric measurement on particles is preformed in situ while coating is being formed.

Second, the Examiner's present interpretation of Drennen is incorrect. Specifically, it is impossible to coat and measure thc coating of the ***same*** particle while it is being coated with the apparatus of Drennen.

In accordance with Drennen, coating and measurement are separate events occurring at differcnt times in different locations in the coating chamber. In this regard, the Examiner's attention is directed to Figures 1 and 2 of Drennen where it is clearly shown that particles **49** are coated in inner chamber **10** of coating chamber **2**. The coating material is delivered through nozzle **12** in inner chamber **10**. The coated particles exit inner chamber **10** and travel downwardly through annular passage **14**. Probe **20** has an upwardly open recess **24** which itself

has an enlarged portion **26** to facilitate entry of a coated particle during its descent in annual passage **14**. Upon entry in open recess **24**, the coated particle is ***trapped*** and then measured.

There is no ambiguity. Drennen discloses that the particles are coated in inner chamber **10** where the coating material is emitted through nozzle **12**. Measurement of a coated particle occurs *after* it has been coated and *after* it has exited inner chamber **10**. Measurement occurs in a separate location after the coated particle has moved downwardly through the annular passage **14** and entered the open recess **24** of probe **20**. At that point, the coated particle is no longer fluidized on an upwardly directed gas flow. Rather, the coated particle is ***trapped*** in open recess **24** of probe **20**. Furthermore, as shown Figure 2 of Drennen, it is possible to withdraw the trapped coated particle from the fluidized bed and perform the measurement off-line.

Therefore, contrary to the Examiner's interpretation, Drennen does not disclose or suggest coating a particle and measuring the coating on the ***same*** particle at the ***same*** time and at the ***same*** spatial location as required by the claimed invention.

VII. There Is No Double Patenting

For all of the forgoing reasons, the claimed invention is not an obvious variant of Folestad in light of Drennen. As acknowledged by the Examiner, Folestad fails to teach the performance of a spectrometric measurement of a single pharmaceutical particle while the ***same*** particle is coated within a fluidized bed. Similarly, as discussed in the preceding Section VI, Drennen does not disclose or suggest the performance of a spectrometric measurement of a single pharmaceutical particle while the ***same*** particle is coated within a fluidized bed. Rather, Drennen discloses the coating of particles within a fluidized bed and measurement of the coated particle in a probe, within or withdrawn from the fluidized bed, while the coated particle is

trapped in a recess of the probe and no longer fluidized on an upwardly directed gas flow. Thus, as correctly stated by the Examiner in the Office Action, mailed January 23, 2004:

> Drennen, III et al fail to teach that the spectrometric measurement on particles is preformed in situ while coating is being formed.

Even when considered in view of Drennen, Folestad continues to fail to teach the performance of a spectrometric measurement of a single pharmaceutical particle while the ***same*** particle is coated within a fluidized bed. None of the other cited patents in combination with Drennen, i.e., Van Laethem, Cody, Maguire, Patel and Woodruff, overcomes this deficiency.

For all of the foregoing reasons, Applicants submit that there is no double patenting. Withdrawal of the obviousness-type double patenting rejection is requested.

CONCLUSION

Applicants submit that pending claims 1, 2, 4-20, 22-25 and 27-53 are in condition for allowance, which action is earnestly solicited. The Commissioner is hereby authorized to charge Deposit Account No. 23-1703 in the event that any fee is required in connection with this communication.

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Respectfully submitted,

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